UNITED STATES DISTRICT COURT

SOUTHERN DISTRICT OF CALIFORNIA

JEFFREY CHIONE AND DEANNA CHIONE,

Plaintiffs,

v.

MEDTRONIC, INC., *ET AL.*,

Defendants.

Case No. 14-cv-01043-BAS(RBB)

ORDER GRANTING DEFENDANTS' MOTION TO DISMISS WITH LEAVE TO AMEND

(ECF No. 6)

On or about February 5, 2014, Plaintiffs Jeffrey Chione and Deanna Chione (collectively "Plaintiffs") commenced this action against Medtronic, Inc., Medtronic USA, Inc., and Medtronic Sofamor Danek USA, Inc. (collectively "Medtronic" or "Defendants") in San Diego Superior Court alleging negligence, strict liability, breach of express and implied warranty, fraud, negligence per se, and loss of consortium. Defendants removed this action to federal court on April 25, 2014 based on diversity of citizenship under 28 U.S.C. § 1441(b). Defendants now move to dismiss this action under Rule 12(b)(6) of the Federal Rules of Civil Procedure. Plaintiffs oppose. (ECF No. 11 ("Opp.").)

The Court heard oral argument on the motion on May 4, 2015. For the following reasons, the Court **GRANTS** Defendants' motion to dismiss with leave to amend. (ECF No. 6.)

I. BACKGROUND

This is a products liability action arising out of Defendants' alleged illegal and off-label[1] promotion of INFUSE Bone Graft ("Infuse"), a medical device manufactured by Defendants. (ECF No. 1-1 ("Compl.") at ¶¶ 1, 8.) Infuse is a surgically implanted medical device containing a genetically engineered protein designed to stimulate bone growth. (*Id*. at ¶ 8.)

On January 12, 2001, Defendants submitted Infuse to the Federal Drug Administration ("FDA") for premarket approval. (*Id*. at ¶ 24.) During the approval process, the FDA Advisory Committee expressed concern about the potential for off-label use of Infuse. (*Id*. at ¶¶ 26, 33.) Nonetheless, on July 2, 2002, the FDA approved Infuse under expedited review. (*Id*. at ¶¶ 24, 25.) Despite numerous studies showing that off-label use of Infuse can lead to "serious, even adverse, events," Plaintiffs claim Medtronic then proceeded to actively promote off-label use, concealing the dangers and its surreptitious effort to promote such off-label use. (*Id*. at ¶¶ 36-44.)

On April 24, 2007, May 22, 2007, and September 9, 2008, Dr. Eric Korsh performed various back surgeries on Mr. Chione using Infuse. (*Id*. at ¶¶ 45, 49). Dr. Korsh used Infuse in an off-label manner. (*Id*. at ¶ 50.) He used Infuse in cervical fusion procedures and a posterior procedure. (*Id*. at ¶¶ 45-49.) Neither of these procedures has been approved by the FDA. (*Id*. at ¶ 50). Plaintiff alleges Defendants "directly and indirectly promoted, trained and encouraged Dr. Korsh to use" Infuse in this manner. (*Id*. at ¶ 51).

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[1] "Off-label" use denotes use of a device in a way or for a purpose not approved by the FDA. (Compl. at ¶ 16.)

Dr. Korsh never informed Mr. Chione (1) that he was using Infuse in an off-label manner, (2) that use of Infuse in a posterior procedure had never been tested or approved by the FDA, (3) that an Infuse "clinical trial utilizing the posterior procedures had been halted due to the serious adverse events that had been experienced," (4) that use of Infuse "could result in unwanted bone growth and migration of the bone to sensitive nerve areas exacerbating her [sic] pain," and (5) of available alternative methods of surgery. (*Id*. at ¶ 52.)

Plaintiffs allege six causes of action: (1) Negligence—largely based on Defendants' failure to warn doctors, the medical community, and the general public of the dangers of the off-label use of Infuse; (2) Strict liability—based on Defendants' promotion of the off-label use of Infuse, impliedly representing such use was safe when Defendants knew it was not; (3) Breach of express and implied warranty—based on Defendants' representations to doctors and members of the public that off-label use was safe and effective; (4) Fraud—based primarily on allegations that Defendants provided inaccurate or misleading information to the medical community which was material to the surgeon's decision to treatment of Plaintiff; (5) Negligence per se—claiming a violation of federal statutes and regulations; and (6) Loss of consortium on behalf of Mr. Chione's spouse, Deanna Chione.

Defendants move to dismiss on the grounds that Plaintiffs' claims are barred by the statute of limitations, both expressly and impliedly preempted by the federal Medical Device Amendments of 1976 ("MDA"), and that Plaintiffs' fraud claims lack particularity.

II. LEGAL STANDARD

A. Rule 12(b)(6)

A motion to dismiss pursuant to Rule 12(b)(6) of the Federal Rules of Civil Procedure tests the legal sufficiency of the claims asserted in the complaint. Fed. R. Civ. P. 12(b)(6); *Navarro v. Block*, 250 F.3d 729, 732 (9th Cir. 2001). The court

must accept all allegations of material fact pleaded in the complaint as true and must construe them and draw all reasonable inferences from them in favor of the nonmoving party. *Cahill v. Liberty Mut. Ins. Co.*, 80 F.3d 336, 337-38 (9th Cir. 1996). To avoid a Rule 12(b)(6) dismissal, a complaint need not contain detailed factual allegations; rather, it must plead "enough facts to state a claim to relief that is plausible on its face." *Bell Atl. Corp. v. Twombly*, 550 U.S. 544, 570 (2007). "A claim has facial plausibility when the plaintiff pleads factual content that allows the court to draw the reasonable inference that the defendant is liable for the misconduct alleged." *Ashcroft v. Iqbal*, 556 U.S. 662, 678 (2009) (citing *Twombly*, 550 U.S. at 556). "Where a complaint pleads facts that are merely consistent with a defendant's liability, it stops short of the line between possibility and plausibility of entitlement to relief." *Id.* at 678 (quoting *Twombly*, 550 U.S. at 557) (internal quotations omitted).

"[A] plaintiff's obligation to provide the 'grounds' of his 'entitle[ment] to relief' requires more than labels and conclusions, and a formulaic recitation of the elements of a cause of action will not do." *Twombly*, 550 U.S. at 555 (quoting *Papasan v. Allain*, 478 U.S. 265, 286 (1986) (alteration in original). A court need not accept "legal conclusions" as true. *Iqbal*, 556 U.S. at 678. Despite the deference the court must pay to the plaintiff's allegations, it is not proper for the court to assume that "the [plaintiff] can prove facts that [he or she] has not alleged or that defendants have violated the…laws in ways that have not been alleged." *Associated Gen. Contractors of Cal., Inc. v. Cal. State Council of Carpenters*, 459 U.S. 519, 526 (1983).

Generally, courts may not consider material outside the complaint when ruling on a motion to dismiss. *Hal Roach Studios, Inc. v. Richard Feiner & Co., Inc.*, 896 F.2d 1542, 1555 n.19 (9th Cir. 1990); *Branch v. Tunnell*, 14 F.3d 449, 453 (9th Cir. 1994) (overruled on other grounds by *Galbraith v. Cnty. of Santa Clara*, 307 F.3d 1119, 1121 (9th Cir. 2002)). "However, material which is

properly submitted as part of the complaint may be considered." *Hal Roach Studios, Inc.*, 896 F.2d at 1542 n.19. The court may also consider documents specifically identified in the complaint whose authenticity is not questioned by the parties. *Fecht v. Price Co.*, 70 F.3d 1078, 1080 n.1 (9th Cir. 1995) (superseded by statute on other grounds); *see also Branch*, 14 F.3d at 453–54. The court may consider such documents so long as they are referenced in the complaint, even if they are not physically attached to the pleading. *Branch*, 14 F.3d at 453–54; *see also Parrino v. FHP, Inc.*, 146 F.3d 699, 706 (9th Cir. 1998) (extending rule to documents upon which the plaintiff's complaint "necessarily relies" but which are not explicitly incorporated in the complaint). Moreover, the court may consider the full text of those documents even when the complaint quotes only selected portions. *Fecht*, 70 F.3d at 1080 n.1. The court may also consider materials of which it takes judicial notice. *Barron v. Reich*, 13 F.3d 1370, 1377 (9th Cir. 1994).

As a general rule, a court freely grants leave to amend a complaint it dismisses. Fed. R. Civ. P. 15(a); *Schreiber Distrib. Co. v. Serv-Well Furniture Co.*, 806 F.2d 1393, 1401 (9th Cir. 1986). The court may deny leave to amend, however, when "[it] determines that the allegation of other facts consistent with the challenged pleading could not possibly cure the deficiency." *Schreiber Distrib. Co.*, 806 F.2d at 1401 (citing *Bonanno v. Thomas*, 309 F.2d 320, 322 (9th Cir. 1962)).

III. DISCUSSION

A. Statute of Limitations

Defendants argue Plaintiffs' claims all fail because they are barred by the statute of limitations. A statute of limitations defense may be raised on a Rule 12(b)(6) motion "[i]f the running of the statute is apparent on the face of the complaint." *Jablon v. Dean Witter & Co.*, 614 F.2d 677, 682 (9th Cir. 1980). In such a case, the motion "can be granted only if the assertions of the complaint, read with the required liberality, would not permit the plaintiff to prove that the statute

was tolled." *Id*. Because the statute of limitations is an affirmative defense, the "defendant has the burden of proving the action is time-barred." *Grisham v. Philip Morris, Inc*., 670 F. Supp. 2d 1014, 1020 (C.D. Cal. 2009) (citations omitted).

Under California law,[2] "personal injury claims based on defective products are subject to a two-year limitations period" regardless of the particular legal theory invoked. *Eidson v. Medtronic, Inc.*, 40 F. Supp. 3d 1202, 1217 (N.D. Cal. 2014) (citing *Soliman v. Philip Morris Inc*., 311 F. 3d 966, 971 (9th Cir. 2002)); Cal. Civ. Proc. Code § 335.1 (statute of limitations is two years for actions claiming "injury to . . . an individual caused by the wrongful act or neglect of another").

The limitations period runs from the moment a cause of action accrues. *See* Cal. Civ. Proc. Code § 312; *Aryeh v. Canon Bus. Solutions, Inc*., 55 Cal. 4th 1185, 1191 (2013). A cause of action accrues at the time it is "complete with all of its elements," which is generally the date of injury. *Norgart v. Upjohn Co*., 21 Cal. 4th 383, 397 (1999); *Rivas v. Safety-Kleen Corp*., 98 Cal. App. 4th 218, 224 (2002) (citing *Jolly v. Eli Lilly & Co*., 44 Cal. 3d 1103, 1109 (1988)). However, that principle is modified by the discovery rule under which accrual is postponed "until the plaintiff discovers, or has reason to discover, the cause of action." *Norgart*, 21 Cal. 4th at 397; *see also Rivas*, 98 Cal. App. 4th at 224-25; *Jolly*, 44 Cal. 3d at 1109; *Pooshs v. Philip Morris USA, Inc*., 51 Cal. 4th 788, 797 (2011). "Discovery of the cause of action occurs when the plaintiff has reason to suspect a factual basis for the action." *Pooshs*, 51 Cal. 4th at 797 (citation and internal quotations omitted); *Jolly*, 44 Cal. 3d at 1110-11.

However, in order to rely on the discovery rule, a "plaintiff whose complaint shows on its face that his claim would be barred without the benefit of the

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[2] A federal court sitting in diversity on a state law claim must apply the state statute of limitations. *Bancorp Leasing & Fin. Corp. v. Agusta Aviation Corp*., 813 F.2d 272, 274 (9th Cir. 1987).

discovery rule must specifically plead facts to show (1) the time and manner of discovery *and* (2) the inability to have made earlier discovery despite reasonable diligence." *Fox v. Ethicon Endo–Surgery, Inc.*, 35 Cal. 4th 797, 808 (2005) (citation omitted). In assessing the sufficiency of the allegations of delayed discovery, the plaintiff has the burden to "show diligence"; "conclusory allegations" will not suffice. *Id*. at 921. "Formal averments or general conclusions to the effect that the facts were not discovered until a stated date, and that plaintiff could not reasonably have made an earlier discovery, are useless." *Anderson v. Brouwer*, 99 Cal. App. 3d 176, 182 (1979).

In the Complaint, Plaintiffs allege discovery of the factual basis for their claims was delayed by virtue of Defendants' actions, including affirmative misrepresentations and omissions of the "true and significant risks associated with [Infuse]." (Compl. at ¶ 54.) As a result of Defendants' actions, Plaintiffs claim "Mr. Chione and non-defendant healthcare providers involved in his surgeries were unaware, and could not have reasonably known or have learned through reasonable diligence, that Mr. Chione's back pain and various symptoms were the result of these acts, omissions, and misrepresentations." (*Id*. at ¶ 55.) Plaintiffs further allege that "Mr. Chione first learned of the risks and problems associated with Infuse and Medtronic's concealment within two years of filing this action." (*Id*. at ¶ 56.) Plaintiffs do not identify in the Complaint when or how Mr. Chione learned of these risks.

Mr. Chione underwent surgeries in which Infuse was used in an off-label manner on April 24, 2007, May 22, 2007, and September 9, 2008. This action was not filed until February 2014, more than five years after Mr. Chione's last surgery. Thus, the running of the statute of limitations is apparent on the face of the Complaint. Plaintiffs do not argue this point. Rather, in their opposition to Defendants' motion to dismiss, Plaintiffs argue the application of the discovery rule. Plaintiffs argue Mr. Chione "could not have suspected Medtronic caused his

injuries until he saw a television announcement detailing issues with the Infuse Bone Graft device in March 2013." (Opp. at p. 26.) Prior to that, Plaintiffs argue "it was impossible for him to have reasonably suspected Infuse was causing his injuries," for the following reasons: (1) Mr. Chione had never heard of Infuse, (2) he was unaware Infuse was used at the time of his surgery, and (3) Mr. Chione was never informed Infuse was the cause of his pain by his doctors. (*Id.*)

In *Eidson*, the court concluded it was plausible the plaintiffs were not on inquiry notice concerning the role Infuse played in the alleged injury until the injured plaintiff's mother saw a commercial about lawsuits involving Infuse. *Eidson*, 40 F. Supp. 3d at 1218. Plaintiffs here seek to add similar allegations. However, they are not presently in the Complaint. Plaintiffs must "specifically *plead* facts to show (1) the time and manner of discovery and (2) the inability to have made earlier discovery despite reasonable diligence," *Fox*, 35 Cal.4th at 808 (emphasis added), and they have failed to do so. As the running of the statute of limitations is apparent on the face of the Complaint and Plaintiffs have failed to sufficiently allege the discovery rule delayed accrual of their claims, Defendants' motion to dismiss is **GRANTED**.

Defendants argue that giving Plaintiffs leave to amend would be futile because the facts Plaintiffs seek leave to add "reveal that Mr. Chione began suffering pain and other symptoms after his surgeries and that he attempted [at that time] to investigate the source of his pain," thus triggering the statute of limitations. (*See* ECF No. 14 at p. 8.) Defendants further argue the only thing Mr. Chione claims he learned within the statute of limitations was that Infuse was allegedly used in an off-label manner. (*Id.*)

However, a claim accrues when the plaintiff "suspects . . . that someone has done something wrong to him." *Soliman*, 311 F. 3d at 971 (citing *Jolly*, 44 Cal. 3d at 1110); *see also Fox*, 35 Cal. 4th at 808 ("[I]n order to employ the discovery rule to delay accrual of a cause of action, a potential plaintiff who suspects that an injury

has been *wrongfully* caused must conduct a reasonable investigation of all potential causes of that injury." (emphasis added)). Plaintiffs contend that they seek to add facts, among others, alleging that Mr. Chione's doctors continually told him his pain was the result of scar tissue. (Opp. at p. 26.) Thus, while Mr. Chione experienced pain and knew a device had been used in his fusion surgery, based on the proposed allegations, it is plausible he did not have reason to suspect that someone had done something wrong to him until March 2013. (*Id.*) Accordingly, the Court grants Plaintiffs leave to amend their Complaint.

IV. CONCLUSION & ORDER

For the foregoing reasons, Defendants' motion to dismiss is **GRANTED WITH LEAVE TO AMEND**. If Plaintiffs wish to amend, they shall do so no later than **May 29, 2015**.

IT IS SO ORDERED.

DATED: May 7, 2015

Hon. Cynthia Bashant
United States District Judge